MAR 17 2004

K033923 1 of 2

APPENDIX B

510(k) PREMARKET NOTIFICATION SUMMARY
(Per 21 CFR 807.92)

THØR DDII IR Lamp Systems

I. Applicant:

THØR International Ltd.
Caer Sidhe
Chiltern Road
Amersham
HP6 5PH
United Kingdom
Telephone: +44 1494 433 736
Facsimile: +44 1494 431 481
Email: james@thorlaser.com

Key Contact: James Carrol

II. Device Name

Proprietary Name:	THØR DD II IR Lamp System
Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.555)
Product Code:	ILY

III. Predicate Device

The THØR DDII IR Lamp System is substantially equivalent to other infrared lamps currently in commercial distribution such as the Super Nova / Acubeam systems manufactured by Light Force Technology, Inc., and BioFlex Professional Therapy System manufactured by Meditech International, Inc.

IV. Intended Use of the Device

The THØR IR Lamp System is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

K033923 2 of 2

V. Description of the Device

The THØR DDII IR Lamp System is a portable, AC and battery operated non-invasive, low level infrared lamp that provides continuous heat therapy at a fixed frequency. The System consists of a Drive Unit/Power Supply that houses the electronics and controls and optional treatment probes that contain the visible and infrared radiating elements. Various Cluster Probes are available accessories with the Drive Unit.

VI. Summary of the Technical Characteristics of the Thor DDII IR Lamp System as Related to the Referenced Predicate Devices.

The THØR DDII IR Lamp System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared diodes to generate topical heating for the purpose of elevating tissue temperatures for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local circulation and the temporary relaxation of muscle. The Systems are intended to be placed directly on the skin to provide heating.

VII. Testing

Testing of the THØR DDII IR Lamp System included functional performance testing and electrical safety testing.

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the THØR DDII IR Lamp System has the same intended uses, with similar functional and performance characteristics. The THØR DDII IR Lamp System is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature[1] and accepted by the Federal Food and Drug Administration.

The THØR DDII IR Lamp System performs as intended and do not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

Thor International Ltd.
C/o M. Joyce Heinrich
Texas Applied Biomedical Services, Inc.
12101 - A Cullen Boulevard
Houston, Texas 77047

Re: K033923
Trade/Device Name: Thor DDII IR Lamp System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: December 15, 2003
Received: January 16, 2004

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT C

INDICATIONS FOR USE

510(k) Number (if known): K033923

Device Name: **THØR DDII IR Lamp System**

Indications for Use:

The THØR DDII IR Lamp System is intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

Prescription Use: X **AND/OR** **Over the Counter Use:** ___
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K033923